Checklist for Contribution of Your Trial/Clinical Study to IMACS Outcomes Repository

Principal Investigator:_____ Email:_____
Trial or Clinical Study
Name:_____
__Natural History Study __Therapeutic Trial

__Trial/clinical study will be completed within the next 3 years:
Please define the date for completion of your trial _____
How many patients will be completed by 04/01/2008 (and that you could release to the outcomes repository)? _____
How many patients will be completed by 12/31/2008 (and that you could release to the outcomes repository)? _____
How many patients will be completed by 12/31/2009 (and that you could release to the outcomes repository)? _____

Date for completion of data entry into the on-line database: _____
Number of patients anticipated to be contributed from your trial or study:_____
Type and number of patients anticipated to be contributed from your trial or study:
__Adult Dermatomyositis: ___# __Adult Polymyositis:___# ___Inclusion body myositis:____#
__Juvenile Dermatomyositis:___# ___Juvenile Polymyositis:____#

__Trial/clinical study will be using all of the IMACS Core Set Activity Measures and required ancillary data forms (outlined in IMACS Repository Requirements)
Which forms are you NOT including in your trial or have discrepancies with?
_____
Are you using both Visual analog scales and Likert scale for Physician Global Activity?_____
Are you using MMT 0- 10 point scale? Or MMT 0 – 5 point scale (please share details if 0 – 5 point scale)? _____ Are you measuring MMT8 or a larger set of muscles?_____
Are you including Physician and Patient/Parent Global Damage and the Myositis Damage Index?_____
Are you including a patient reported outcome measure (SF-36 or CHQ-PF50)?_____
Are you including any of the extended forms in your trial, including CMAS and DAS? Which ones?_____

__Trial/clinical study meets regulatory requirements (specify below)
___All participating centers hold a Federal Wide Assurance agreement and their IRB's are registered with the Department of Health and Human Services

___The trial/clinical study has specific ethics or IRB approval for contribution of the data to IMACS, or
___The trial/clinical study is no longer under IRB review (the study has terminated), and data will be contributed anonymized (with an exemption application).

___ A Data Transfer Agreement will be needed, or
___ A Data Transfer Agreement will not be needed to contribute data to the IMACS Repository.

__Data can be entered into the IMACS Oracle database, with access only to the principal investigator and their designees until the trial's conclusion, or
__Data from the trial/clinical study can be contributed by contributing a database for this trial/clinical study accompanied by a codebook of variables and variable names and a frequency distribution of variables:

What format is your database if you do not plan on-line data entry into the IMACS database? _____
Will you develop a codebook and frequency distribution of your variables?_____
Do you have ancillary data that can be contributed as a separate database for archiving in the registry?_____

__Are you willing to serve on the IMACS Research Advisory Committee? _____